DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sarah Parsons
Associate, Regulatory Affairs
Immunodiagnostics Systems
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

MAR 11 2004

Re: P030026
Vitros Immunodiagnostic Products Anti-HBc IgM Reagent Pack and *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator

Dear Ms. Parsons:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) and issued an approval order on March 4, 2004. We inadvertently made an error in the paragraph describing the expiration dating for the *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack and *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator for various storage conditions. In your approval order the paragraph stated:

> Expiration dating for the *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack and *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator have been established and approved for 26 weeks when stored unopened and continuously at 2 – 8 °C. On instrument open-reagent pack storage has been established for eight weeks when the temperature of the reagent pack is maintained at 2 – 8 °C and left at room temperature for no longer than 30 minutes. Open calibrator storage has been established for thirteen weeks when stored at 2 – 8 or -20 °C with no more than one freeze-thaw cycle. *Vitros* ECi Immunodiagnostic System calibration for the anti-HBc IgM assay has been established for 28 days.

The correct paragraph is:

> Expiration dating for the *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack and *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator have been established and approved for 26 weeks when stored unopened and continuously at 2 – 8 °C. On instrument storage for open reagent packs has been established for eight weeks when the temperature of the reagent packs are maintained at 2 – 8 °C. Open calibrator storage has

been established for thirteen weeks when stored at 2 – 8 or -20 °C with no more than one freeze-thaw cycle. *Vitros* ECi Immunodiagnostic System calibration for the anti-HBc IgM assay has been established for 28 days. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact Thomas E. Simms at (301) 594-2096.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

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MAR - 4 2004

Re: P030026
Vitros Immunodiagnostic Products Anti-HBc IgM Reagent Pack and *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator
Filed: June 27, 2003
Amended: February 9, 2004
Procode: LOM

Dear Ms. Parsons:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack and Anti-HBc IgM Calibrator. These devices are indicated for:

1. *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack:

   For the *in vitro* qualitative detection of IgM antibody to hepatitis B core antigen (anti-HBc IgM) in human adult and pediatric serum and plasma (heparin, EDTA and citrate) and neonate serum using the VITROS ECi Immunodiagnostic System. Assay results, in conjunction with other serological and clinical information, may be used for the laboratory diagnosis of individuals with acute or chronic hepatitis B.

2. *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator:

   For use in the calibration of the *Vitros* Immunodiagnostic System for the *in vitro* qualitative detection of IgM antibody to hepatitis B core antigen (anti-HBc IgM) in human serum and plasma (EDTA, heparin or citrate).

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for the *Vitros* Immunodiagnostic Products Anti-HBc IgM Reagent Pack and *Vitros* Immunodiagnostic Products Anti-HBc IgM Calibrator have been established and approved for 26 weeks when stored unopened and continuously at 2 – 8 °C. On instrument open-reagent pack storage has been established for eight weeks when the temperature of the reagent pack is maintained at 2 – 8 °C and left at room temperature for no longer than 30 minutes. Open calibrator storage has been established for thirteen weeks when stored at 2 – 8 or -20 °C with no more than one freeze-thaw cycle. *Vitros* ECi Immunodiagnostic System calibration for the anti-HBc IgM assay has been established for 28 days.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Thomas E. Simms at 301-594-2096.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
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Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure